

### REMARKS

The Office Action mailed June 30, 2003, has been received and reviewed. Claims 1 through 35 are currently pending in the application, of which claims 1 through 21 are currently under examination. Claims 22 through 35 are withdrawn from consideration as being drawn to a non-elected invention, and are accordingly canceled herein. Claims 1 through 21 stand rejected. Applicants have amended claim 2 and canceled claims 22 through 35. All claim amendments and cancellations are made without prejudice or disclaimer and applicants reserve the right to pursue such claims in one or more related applications. Reconsideration of the application as amended herein is respectfully requested.

#### **35 U.S.C. § 112 Claim Rejections**

Claim 2 stands rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. The Office Action states that insufficient antecedent basis for the language "the detection" in line 1 is provided. Applicants have amended claim 2 to address this issue and respectfully submit this rejection should be withdrawn and the amended claim allowed.

#### **35 U.S.C. § 102(e) Anticipation Rejections**

##### *Anticipation Rejection Based on U.S. Patent No. 5,747,274 to Jackowski*

Claims 1 through 21 stand rejected under 35 U.S.C. § 102(e) as assertedly being anticipated by U.S. Patent No. 5,343,274 to Jackowski ("Jackowski"). Applicants respectfully traverse this rejection, as hereinafter set forth.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

The Office Action states the Jackowski discloses the elements of the claims, including

“continuing the determination until the analyte has been reliably determined to be present in an amount indicative of the metabolic or disease state, see column 29, lines 51-63” (Office Action at pages 3-4). Independent claim 1 recites the elements of:

substantially simultaneously determining concentrations of each of the plurality of analytes in the sample;  
**continuing the substantially simultaneous determination until the at least one analyte has been reliably determined to be present in an amount indicative of the metabolic or disease state (emphasis added).**

Applicants respectfully submit that Jackowski fails to disclose the elements of “continuing the substantially simultaneous determination until the at least one analyte has been reliably determined to be present in an amount indicative of the metabolic or disease state.” Instead, Jackowski discloses a method for making a single determination occurring at single point in time, not continuing a single assay. The passage cited in the Office Action, at column 29, lines 51 to 63 of Jackowski merely states what may be indicated by the detection of the presence of three different diagnostic analytes, it does not refer to a “continuing a substantially simultaneous determination.” At column 10, lines 5 to 18, Jackowski summarizes the invention disclosed therein as:

More specifically, the present method comprises:

- i. contacting a sample, such as blood, serum or plasma, suspected of having the markers with at least three binding partners, e.g., antibodies, wherein at least one of each binding partner is specific for one of each marker suspected of being present in the sample, under conditions that provide for immunospecific binding of the binding partner to the marker for which it is specific so as to form a binding partner-marker binding pair; and
- ii. reacting the antibody-marker binding pair with a second capture antibody to form a multiple antibody-maker composite;
- iii. detecting the presence of the composite.

In each of the embodiments of the method that are described in Jackowski the “detecting” is only effected once, following the “reacting” (*see, e.g.* Jackowski at column 22, lines 2-12; column 29, lines 50-63, column 30, lines 18-26 and column 35, lines 60-68). As Jackowski merely describes that “detecting” is effected following “reacting” without describing, teaching, or suggesting that

the act of “detecting” may be anything other than an end point assay, Jackowski lacks any express or inherent description of “continuing” a determination “until at least one analyte has been reliably determined to be present in an amount indicative of [a] metabolic or disease state.”

At column 27, lines 38 through 44, Jackowski does state that:

The methods and corresponding kits of the present invention are capable of incorporation and practice within a variety of optical measurement systems. Specifically, while the kits and materials of the present invention may be practiced in an immunoassay format, such format itself is capable of embodiment in a variety of optoelectronic detection systems.


However, the incorporation of a single outcome assay into a different measurement system still results in a single outcome assay.

Further, in describing the preferred embodiments, Jackowski describes a test kit into which a sample is loaded that provides a single outcome to detect the presence of analytes, finally stating that “if the test kit is used at timed intervals the increase or decrease in marker concentration can also be determined and used as a diagnostic tool.” (Jackowski column 32, lines 27-32). The Jackowski method is thus directed to detecting a marker in a sample at a single time point, giving a single output and allows for the repetition of the single time point assays with different samples at different times. (*Ibid.*). It thus does not disclose “**continuing the substantially simultaneous determination** until the at least one analyte has been reliably determined to be present in an amount indicative of the metabolic or disease state.” Accordingly, applicants respectfully submit that independent claim 1 defines over Jackowski and request it be allowed, with claims 2-21 dependent therefrom.

**CONCLUSION**

All pending claims are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Office determine that additional issues remain which might be resolved by a telephone conference, the Examiner is respectfully invited to contact Applicants' undersigned attorney.

Respectfully submitted,



Bretton L. Crockett  
Registration No. 44,632  
Attorney for Applicants  
TRASKBRITT  
P.O. Box 2550  
Salt Lake City, Utah 84110-2550  
Telephone: 801-532-1922

Date: September 29, 2003  
BLC